Longitudinal ruptures of polyester knitted vascular prostheses

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Aim: **The purpose of the study was the characterization of a type of rupture occurring on warp-knitted polyester vascular prostheses.**

Materials and Methods: **We studied 20 cases of warp-knitted polyester vascular prostheses that were explanted from humans that showed a longitudinal rupture as a part of a collaborative retrieval program. All the prostheses were immediately fixed in a 10% formaldehyde solution after their explantation in the operating room. The clinical data of these cases were recorded. The explants were photographed, washed to eliminate the surrounding tissues, and photographed again. The ruptures were characterized with macroscopic examination, optical stereomicroscopy, and scanning electron microscopy.**

Results: **The mean duration of implantation of the prostheses was 16.0 ± 3.3 years (range, 9-20.7 years). The prostheses were Cooley Double Velour (n = 15) and Microvel Double Velour (n = 5). There were 16 aortobifemoral bypass grafts, 1 aorto-biiliac, 1 aorto-aortic, 1 iliofemoral, and 1 axillobifemoral. The longitudinal ruptures occurred on two specific parts of the prostheses: the guide line (6 cases) and the remeshing line (11 cases). In three cases both lines were affected. Scanning electron microscopy showed major degradation of the trilobar filaments of the velour and gradual ruptures of the flat filaments of the remeshing and guide lines.**

Conclusions: **In this study, we have identified a specific mechanism of late (9-20 years) longitudinal rupture of knitted polyester prostheses consisting of degradation of the polyester filaments along the remeshing and guide lines that run the length of the graft. (J Vasc Surg 2001;33:1015-21.)**

Long-term degradation is a complication of polyester vascular prosthesis that may lead to dilatation or prosthetic ruptures.[1-3] Degradation is probably related to multiple factors such as the design of the textile structure, alterations of the prosthesis during the manufacturing process or during the implantation by handling or application of clamps, and, possibly, secondary physicochemical alterations when the prosthesis is exposed to the chronic foreign body inflammatory reaction and to the systolo-diastolic arterial stress.[4]

The first cases of ruptures of textile polyester vascular prostheses occurred on weft-knitted structures. A weft knit is the simplest form of knitting because a single yarn travels in the weft direction forming each row of stitches. A second yarn, traveling with the body yarn, can be used to form velour loops perpendicular to the surface. These ruptures consisted in holes and transversal or longitudinal tears and more often were multiple and observed on the overall prosthesis.[2,5-8] Consequently, weft-knit structures have been discarded because of their poor long-term stability and replaced with warp-knit structures. Warp-knitted structures are more complex than weft knits. Yarns are assembled in the warp or machine direction similar to threading a weaving loom. A series of needles interact with these yarns to form the stitches. Warp-knit structures, mainly lock-knit structures, demonstrated good mechanical performances in terms of long-term stability. However, sporadic cases of ruptures of warp-knit structures have been reported in the literature. Sometimes they consisted of general degeneration of the textile with huge degradation of the fibers and complete destructuration of the prosthesis with multiple holes and tears. These degenerations of the first degeneration of warp-knitted velour prostheses were probably related to changes in the manufacturing process of both Cooley Double Velour and Microvel Double Velour grafts (Meadox Medical, Oakland, NJ) where trilobar filaments were substituted for cylindrical filaments in the velour yarn in an attempt to produce a velour of superior quality. This modification was discontinued in 1981, when degradation tests demonstrated that cylindrical filaments were more durable.[9] However, a limited number of cases that showed longitu-

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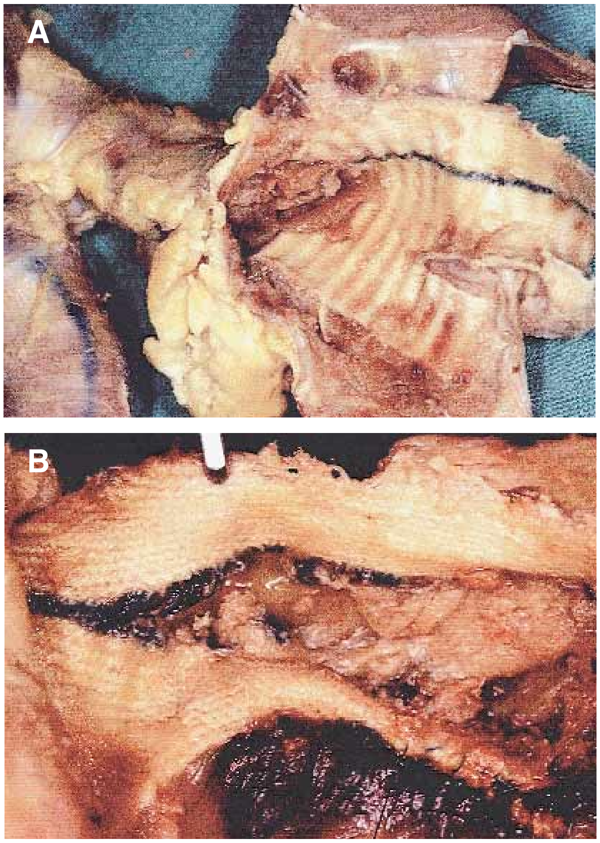

Fig 1. Macroscopic examination of Cooley Double Velour prosthesis implanted as axillofemoral bypass graft for 14 years (case no. 13). **A,** Ruptures on remeshing line. **B,** Rupture on guide line.

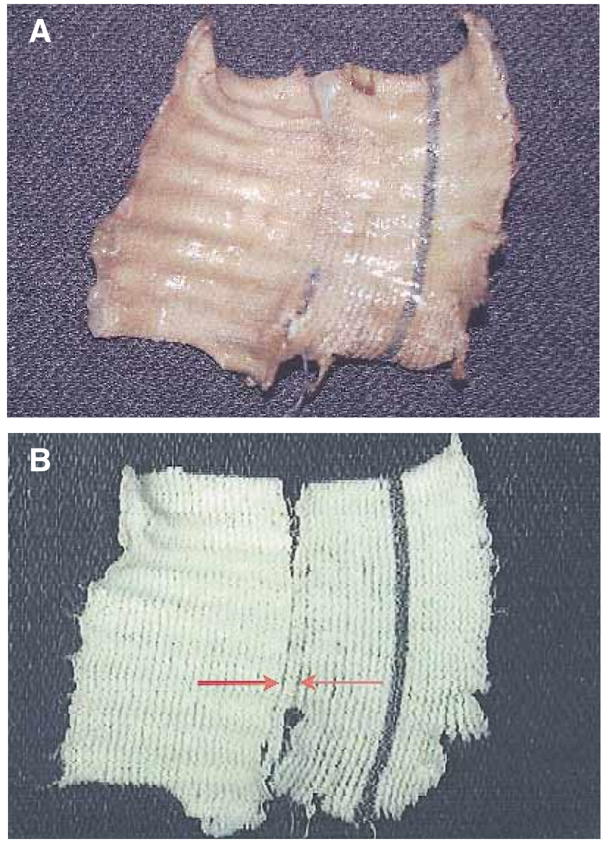

Fig 2. Macroscopic examination of Cooley Double Velour prosthesis implanted as aortobifemoral bypass graft for 13 years (case no. 14) and presenting a rupture on remeshing line at femoral anastomosis of a limb. **A,** After explantation; **B,** after cleaning.

dinal ruptures without a morphologic degradation of the remaining textile have been reported.[10,11]

The goal of the current study was to analyze the characteristics of a series of 20 prostheses explanted because of the presence of at least one longitudinal rupture to understand their mechanisms.

MATERIALS AND METHODS

The explanted prostheses

We analyzed 20 warp-knitted polyester vascular prostheses that showed longitudinal ruptures that were collected as part of our European collaborative retrieval program from 1992 to 1999. For each case we noted the model of the prosthesis, the surgeon who explanted the prosthesis (if known), the year of the implantation, the duration of implantation, the site of implantation, and the reason for explantation. After explantation, the prostheses were fixed in a 10% formaldehyde solution.

Processing of the prostheses

At the time of their reception in our laboratories, the prostheses were photographed and macroscopically analyzed with the naked eye.

The prostheses were then cleaned to complete the following investigations. They were immersed in a 10% sodium hypochlorite solution with soft agitation for 3 hours. They were then rinsed in distilled water, and hypochlorite remnants were neutralized with a 0.5% hydrogen peroxide solution. The prostheses were rinsed again in distilled water, dried, and stored. The prostheses were then photographed and observed to determine the area where the ruptures occurred. We also characterized the macroscopic aspect of the textile structure of the nonruptured areas. We measured the perimeter of the prosthesis when its entire circumference had been sent to calculate its approximate diameter.

Microscopic examination. The prostheses were studied under a magnification optical system to determine the model of prosthesis through analysis of the textile structure and the presence of trilobar or cylindrical filaments in the velour structure. This was compared with our database of virgin prostheses.

Scanning electron microscopy. Scanning electron microscopy (Hitachi S-2360N; Elexience, Verrières le Buisson, France) was used to determine the lesions of the textile structure. The specimens were studied without metalization, in partial vacuum conditions (0.1-0.15 torr), and under an accelerating voltage from 8 to 18 KeV. These conditions allowed us to be nondestructive toward the specimens to preserve them for further investigations depending on our research, but allowed a maximum rate of magnification of 200. We studied the aspect of the longitudinal ruptures and the aspect of the filaments inside the yarns.

RESULTS

The prostheses

The main characteristics of the explanted prostheses are given in the Table (online only).

Year of implantation of the prostheses. The year of implantation of the prosthesis was obtained by the explanting surgeon. All of the prostheses were implanted before 1985. Two prostheses were implanted in 1976, 1 in 1977, 2 in 1978, 5 in 1979, 2 in 1980, 4 in 1981, 2 in 1982, 1 in 1983, and 1 in 1985.

Models of prostheses. Frequently, the model of the prosthesis was unknown to the surgeon who explanted the prostheses, mainly because the prostheses were implanted long ago or in another institution. After analysis of the textile structure under optical magnification, we definitively determined the model of the prostheses. In 15 cases there were Cooley Double Velour models. All of these prostheses included trilobar filaments in the yarns of the velour. In five cases there were Microvel Double Velour models. Two prostheses, implanted in 1983 and 1985, included cylindrical filaments in the yarns of the velour. The three other cases included trilobar filaments.

Mean duration of implantation of the prostheses. The mean duration of implantation of the prostheses was 16.0 ± 3.3 years (range, 9-20.7 years).

Site of implantation of the prostheses. All of the prostheses were implanted for an aortic bifurcation with an anatomic bypass graft in 19 cases (16 aortobifemoral, 1 aorto-biiliac, 1 aorto-aortic, and 1 iliofemoral bypass grafts) and an extra-anatomic bypass graft in 1 case (1 axillobifemoral bypass graft). The rupture was observed on the body of a bifurcated graft or on a graft with a diameter more than 14 mm in three cases. In the 17 remaining cases the rupture was located on a limb of the bifurcated graft or on a graft with a diameter less than 10 mm. The ruptures were mostly located near the distal anastomosis of the limb. The axillofemoral prosthesis demonstrated multiple ruptures on the overall length of the axillofemoral and femorofemoral branches of the prostheses.

Reasons for the explantation of the prostheses. The main reason for the reoperation of the patient was the diagnosis of a false aneurysm. The false aneurysms were asymptomatic and mostly located in the groin. Aneurysm thrombosis occurred in two cases, leading to limb loss in one. None of the prostheses were explanted for a dilatation.

Macroscopic examination of the prostheses

The ruptures appeared as longitudinal ruptures on two areas of the prosthesis: the guide line and the remeshing line. The ruptures resembled a complete disruption of the textile, rarely extending to the anastomoses. The false aneurysms had a usual appearance with a fibrous wall and thrombus inside. The naked eye examination of the explanted grafts showed that the ruptures occurred on the guide line in 6 cases, on the remeshing in 11 cases, and on both lines in 3 cases (Figs 1-3).

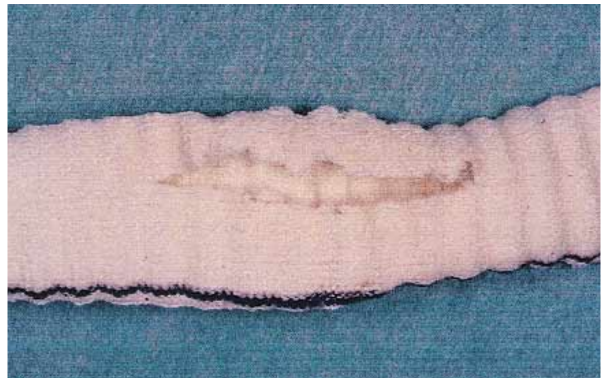

Fig 3. Macroscopic examination of Cooley Double Velour prosthesis implanted as aortobifemoral bypass graft for 22 years (case no. 17) and presenting a rupture at femoral anastomosis of a limb.

The naked eye examination of the cleaned prostheses showed that the ruptures occurred on a textile structure, which did not seem to be degraded. The exception was in one case where a complete degradation of the textile structure was observed. Associated ruptures or degradations were often observed on the alternative line, which was not macroscopically the site of the main rupture leading to the false aneurysm. The main diameter of the prostheses ranged between 10 and 12 mm, which may represent an estimated dilatation of 25% to 50% if we assume that in our experience the most frequent diameter of a limb implanted as an aortobifemoral bypass graft is 8 mm. Two prostheses probably appeared with a higher degree of dilatation because their diameters were measured at 14 and 16 mm for a limb (Table, online only).

Scanning electron microscopy

The specimens were examined under scanning electron microscopy on the external and internal surfaces of the standard knit, the remeshing line, and the guide line. The standard knit demonstrated major lesions of the trilobar filaments constituting the velour. In general, they were completely broken with transversal fractures. This aspect was particularly observed on the external surface of the prostheses, where the velour sometimes completely disappeared. The flat filaments of the standard knit appeared rare to frequent transversal breaks. Under scanning electron microscopy, the remeshing line appeared as two columns of stitches that were very close. The examination of the ruptured remeshing lines showed that the trilobar filaments of the velour were all ruptured with a complete destruction of the velour. The ruptures occurred in all

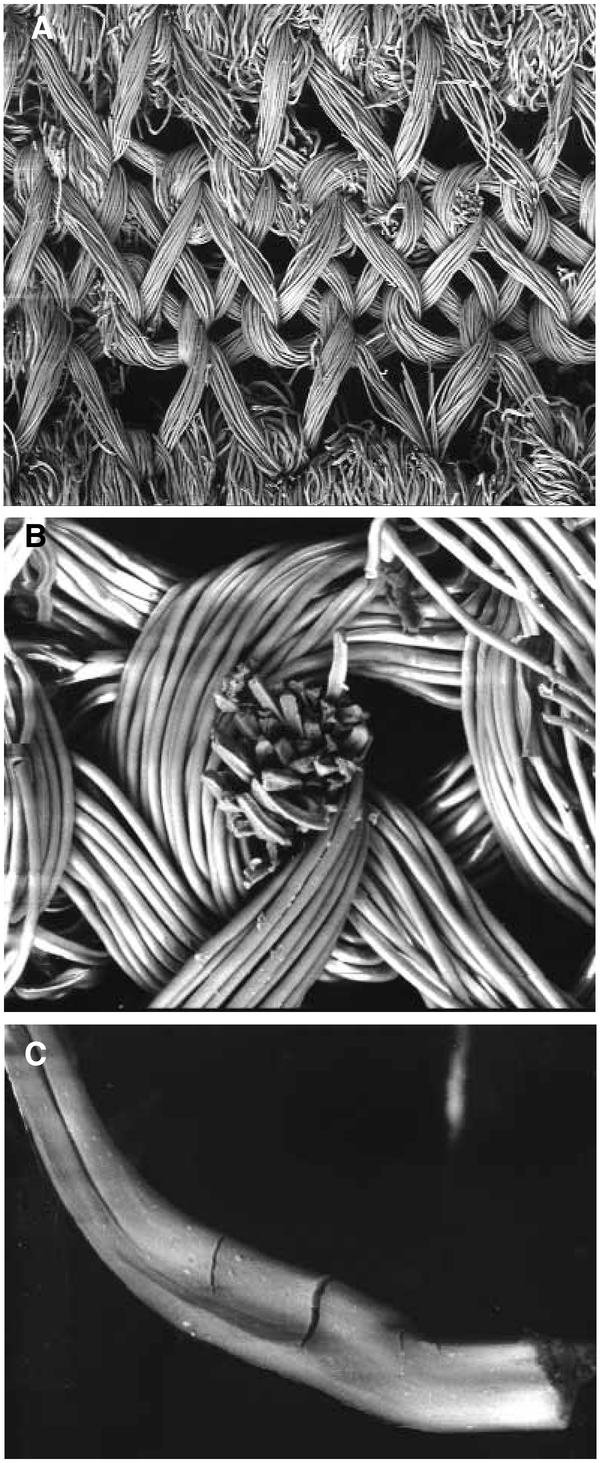

Fig 4. Scanning electron microscopy examination of Cooley Double Velour prosthesis implanted as aortobifemoral bypass graft for 14 years (case no. 9) and presenting a rupture on remeshing line at femoral anastomosis of a limb. Internal view. **A,** Note total destruction of velour structure on both sides of remeshing line (×40). **B,** Transversal breaks of trilobar filaments (×200). **C,** Fissurations and transversal breaks of trilobar filaments (×1250).

Fig 5. Scanning electron microscopy examination of Cooley Double Velour prosthesis implanted as aortobifemoral bypass graft for 17 years (case no. 10) and presenting a rupture on remeshing line at femoral anastomosis of a limb. External view. Note total rupture of flat and trilobar filaments on both sides of remeshing line.

instances on the flat filaments of the yarns between the two columns of the remeshing line and the first column of the standard knit. The breaks of the flat filaments were perpendicular to their axes. The yarns at the end of the rupture showed numerous ruptures of filaments (Figs 4-6). The guide line showed the same aspect of knitting under scanning electron microscopy. The examination of the areas of rupture demonstrated a complete rupture of all of the trilobar filaments of the velour. The flat filaments were transversely broken with an aspect of incomplete and gradual rupture at the edges of the ruptures. At least in the absence of macroscopic rupture on remeshing or guide lines, alteration consisting mainly of an increase of the distance between the columns of stitches was often observed.

DISCUSSION

The current study of 20 explanted grafts coming from a collaborative retrieval program allowed us to characterize a peculiar kind of degeneration of polyester warp-knitted vascular prostheses, the longitudinal ruptures. They were previously reported as sporadic cases in the literature.[10,11] Other cases of ruptures that have also been reported on warp-knitted prostheses did not provide a precise description of the morphology of rupture.[12-17] For the first time, our collaborative program enabled us to analyze a large series of ruptures that appeared with the same characteristics because they were all longitudinal, they all occurred on specific areas, and they involved models of prosthesis constructed by the same manufacturer.

The prostheses involved were all manufactured by the same company that produced two models of warp-knitted prostheses including a double velour structure. The velour yarns of the Cooley Double Velour and of the first model of the Microvel Double Velour were made of trilobar filaments because those of the second model were made of cylindrical filaments. This complication occurred after a long time of implantation. The mean time was about 16 years in the series. Only one prosthesis was implanted before 10 years.

The true incidence of structural failure of vascular prostheses is difficult to estimate because of the following additional reasons. Most patients are not followed up for long periods, and few of those who are undergo periodic appropriate studies (eg, ultrasonography or computed tomography scanning) to evaluate graft integrity. It is also probable that fewer cases are reported because of fear of litigation, especially when failure occurred in a graft removed from the market place. At least there are no suitable means of determining how many patients have died of graft failure because autopsies are not always performed and death may have been attributed to other causes. Sporadic cases of complication of prostheses are reported in the literature. However, the lack of information on the model of the prostheses involved, the description of the rupture, and the ultrastructural investigations performed make the analysis of literature difficult. Regarding these published cases, ruptures of prostheses seem extremely rare. In 1997 Wilson et al[16] reported that 68 cases of degradation of polyester prostheses were reported to the US Food and Drug Administration, which is obviously in all likelihood far from accurate because many cases are not reported to avoid an investigation. Twenty-one prostheses were "Dacron double Velour" that have been implanted between 1977 and 1983 for a mean duration of implantation of 7.4 years (range, 4-18 years). We started our collaborative retrieval program in 1992 and received four prostheses that appeared with longitudinal rupture from 1992 to 1994. The presentation of our program and of our interest for these complications to the societies of vascular surgeons allowed us to collect 16 other cases in the 5 following years. In our opinion, the number of ruptures is underestimated, and we think that, as already experienced, the number of cases declared will increase with growing information of the surgical community, with a diffusion of the facilities to store and send the prostheses (eg, explantation kits, medical forms) and with the insurance to the surgeon to obtain objective information from an independent group. For the true incidence of this complication it is necessary to obtain not only the number of incidents but also the number of each model of prostheses implanted in the same population. This could be achieved by studies with a long-term follow-up. However, longitudinal series did not include a sufficiently long follow-up to observe these cases of long-term degradation. Despite a probably low rate of delayed rupture of polyester prostheses, this complication remains severe for the patient. In all cases the diagnosis of a false aneurysm requires a reoperation for the patient to prevent hemorrhagic or thrombotic complications that may impair the life of the patient or lead to a limb amputation as observed in our series.

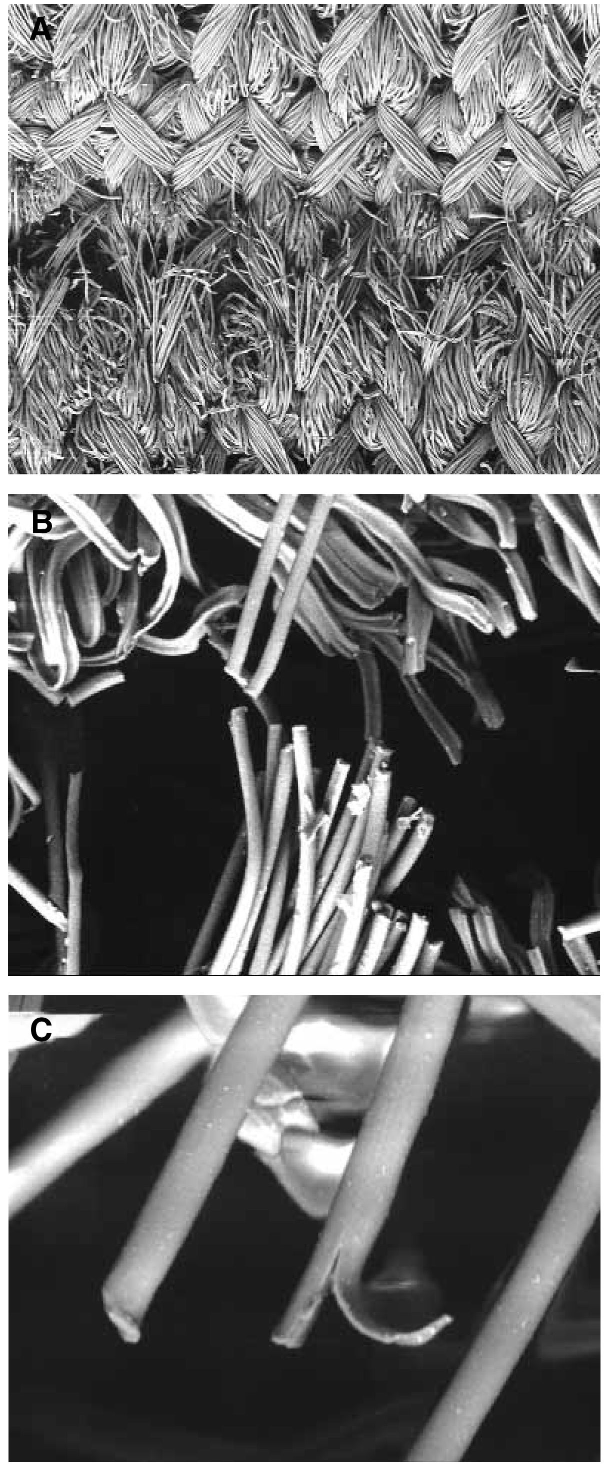

Fig 6. Scanning electron microscopy examination of Cooley Double Velour prosthesis implanted as aortobifemoral bypass graft for 20 years (case no. 19) and presenting a rupture on remeshing line at body of prosthesis. Internal view. **A,** Note typical aspect of gradual rupture of flat yarns (×40). **B,** Fatigue ruptures of cylindrical filaments and degeneration of trilobar filaments (×250). **C,** Fatigue rupture of cylindrical filaments (×800).

The degradation of polyester textile prostheses is probably related to multiple factors. The design of the textile structure is important because ultralight-weight weft-knitted grafts have shown their poor stability in the past.[2,5-8] In contrast to this paper, in which localized ruptures of certain graft regions are demonstrated, general degradation of the textile structure by hydrolysis has been proved.[18,19]

The macroscopic analysis of the explanted prostheses demonstrated that longitudinal ruptures always occurred in two specific areas of the prosthetic structure: the guide line and the remeshing line. The guide line is performed by incorporation of a dyed yarn in the knit and is created to avoid twists of the prosthesis at the time of its implantation. The remeshing line is created by the technique of knitting. Two bands are simultaneously knitted and are joined to create a tube. These two lines may be considered as areas of weakness because we observed longitudinal ruptures on these two specific areas of the knit and not on the standard knit. The analysis of the explanted grafts with scanning electron microscopy demonstrated that the trilobar filaments constituting the velour structure were highly damaged on most grafts. We can consequently assume that the mechanism of these ruptures may be related to a weakening of these yarns during the manufacturing process, probably during the step of knitting. We may also propose that the mechanisms of the damages of the yarns created a heterogeneity of behavior of the filaments inside the yarns because we observed an aspect of gradual rupture of the filaments at the edges of the rupture. These damages may probably be related to important stresses applied to the yarns in this specific area. These stresses are probably more important during the knitting of small diameter protheses because we found the ruptures more frequently on the limbs of the prostheses than on the body despite the higher stresses applied to their wall after implantation and exposure to the arterial flow. The guide line has the same structure of knitting as the standard knit, except for the incorporation of a dyed yarn in this area. An examination of the areas of rupture demonstrated a complete rupture of all of the trilobar filaments of the velour. The flat filaments were transversely broken with an aspect of incomplete and gradual rupture at the edges of the ruptures. An explanation for these ruptures may be a weakening of the dyed yarn by the process of dyeing itself that may modify the macromolecular structure of the polymer. However, considering the few cases of ruptures reported in the literature and their late occurrence, multiple factors are probably necessary to lead to rupture. The remeshing and guide lines of these two models of prostheses may be considered as areas of weakness. Additional damages of the prostheses before, during, and after the implantation may increase the degradation of the polymer and create conditions favorable for the onset of a complication on a preexistent area of weakness.

In conclusion, we demonstrated that the longitudinal ruptures observed on the Cooley Double Velour and the Microvel Double Velour prostheses occurred on two specific areas that may be considered as areas of weakness. The mechanism of these ruptures is unknown, but is probably related to the knitting technique for the remeshing line or to the dyed yarns for the guide line. However, we think that it is only reasonable to set up a systematic program of clinical and duplex scan follow-up of these two models of prostheses implanted for more than 10 to 15 years.

Further studies will involve an extension of our retrieval program with an enhanced information of vascular surgeons to get more accurate epidemiologic data for each kind of degenerative complication. We will set up a protocol of an in vitro study of virgin Cooley Double Velour and Microvel Double Velour prostheses to determine by physical and chemical analyses that the remeshing and guide lines could be considered as predictable areas of weakness before the implantation of the prosthesis. The same technique will also have to be performed on different models of prostheses more recently commercialized to know if all models may present such ruptures and to explain their mechanisms. Such an in vitro program will probably contribute in a better knowledge of the law behavior of polyester vascular prostheses and in an optimization of their manufacturing process.

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REFERENCES

1. Guidoin R, Chakfé N. Aneurysmal deterioration of arterial substitutes. In: Ernst CB, Stanley JC, editors. Current therapy in vascular surgery. Toronto, Philadelphia, B.C. Decker Ed; 1990. p. 324-8.
2. Berger K, Sauvage LR. Late fiber deterioration in Dacron arterial grafts. Ann Surg 1981;193:477-91.
3. Nunn DB, Freeman MH, Hudgins PC. Postoperative alterations in size of Dacron aortic grafts: an ultrasonic evaluation. Ann Surg 1979; 189:741-5.
4. Pourdeyhimi B, Wagner D. On the correlation between the failure of vascular grafts and their structural and material properties: a critical analysis. J Biomed Mater Res 1986;20:375-409.
5. Ottinger MB, Rutherford RB, Skinner DB. An unusual complication of axillo-femoral bypass. Surgery 1972;72:769-71.
6. Ottinger LW, Darling C, Wirthlin LS, Linton RR. Failure of ultralightweight knitted Dacron grafts in arterial reconstructions. Arch Surg 1976;111:146-9.
7. Hussey HH. Arterial replacement: failure of synthetic prostheses [editorial]. JAMA 1976;235:848.
8. Lynn RB. Knitted Dacron ultralight weight grafts: a warning. Can J Surg 1979;22:593.
9. Nunn DB. Structural failure of Dacron arterial grafts. Semin Vasc Surg 1999;12:83-91.
10. Blumenberg RM, Gelfand ML. Failure of knitted Dacron as an arterial prosthesis. Surgery 1977;81:493-6.
11. Trippestad A. Late rupture of knitted Dacron double velour arterial prostheses. Acta Chir Scand 1985;151:391-5.

12. Cooke PA, Nobis RA, Stoney JR. Dacron aortic graft failure. Arch Surg 1974;103:101-3.
13. Yashar JJ, Richman MH, Dyckman J, Witoszka M, Burnard RJ, Weyman AK, et al. Failure of Dacron prosthesis cause by structural defect. Surgery 1978;84:659-63.
14. Nucho RC, Gryborski WA. Aneurysms of a double velour aortic graft. Arch Surg 1984;119:1182-4.
15. Vrancken Peeters MT, Voorwinde A, MacKaay AJ, Butzelaar RM. Late rupture of femoropopliteal Dacron grafts: a rare complication. Eur J Vasc Endovasc Surg 1996;11:243-6.
16. Wilson SE, Krug R, Mueller G, Wilson L. Late disruption of Dacron aortic grafts. Ann Vasc Surg 1997;11:383-6.
17. Watanabe T, Kusaba A, Kuma H, Kina M, Okadome K, Inokuchi K. Failure of dacron arterial prostheses caused by structural defects. J Cardiovasc Surg 1983;24:95-100.
18. Riepe G, Loos J, Imig H, Schroder A, Schneider E, Petermann J, et al. Long-term in-vivo alterations of polyester vascular grafts in humans. Eur J Vasc Endovasc Surg 1997;13:540-8.
19. King M, Guidoin R, Blais P, Garton A, Gunasekera KR. Degradation of polyester arterial prostheses: a physical or chemical mechanism? In: Fraker AC, Griffin CD, editors. Corrosion and degradation of implant materials: second symposium, ASTM STP 859. Philadelphia: American Society for Testing and Materials; 1985. p. 294-307.

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Please see commentary by Dr Daniel Nunn on pages 1131-2.